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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,035	05/02/2005	Fei Huang	D0185 PCT	8131

23914 7590 07/06/2007

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EXAMINER	
LIU, SUE XU	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
07/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,035	HUANG ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

Claims 1-40 are currently pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-8, drawn to a predictor set comprising a plurality of polynucleotides.

Group 2, claim(s) 9-16, drawn to a predictor set comprising a plurality of polypeptides.

Group 3, claim(s) 17(in part)-21, and 25, drawn to a method of predicting whether a compound is capable of modulating the activity of cells using a predictor set comprising polynucleotides.

Group 4, claim(s) 17(in part), and 21-24, drawn to a method of predicting whether a compound is capable of modulating the activity of cells using a predictor set comprising polypeptides.

Group 5, claim(s) 26-28, drawn to a plurality of cell lines for identifying polynucleotides and polypeptides.

Group 6, claim(s) 29-31(in parts), drawn to a method of identifying polynucleotides.

Group 7, claim(s) 29-31(in parts), drawn to a method of identifying polypeptides.

Group 8, claim(s) 32(in part), 33-36, drawn to a method for predicting whether an individual requiring treatment for a disease state using polynucleotides as markers.

Group 9, claim(s) 32(in part), 37-40, drawn to a method for predicting whether an individual requiring treatment for a disease state using polypeptides as markers.

***Further Restriction* (Note: This is not species selection.)**

The inventions listed as Groups 1-9 are subjected to further restrictions as set forth below:

A.) ***For invention Groups drawn to "a plurality of polynucleotides"*** *(including the method Groups)*: Applicants are further requested to elect a single specific combination of polynucleotides identified by their corresponding SEQ ID NOs. (Applicants are requested to specify the number of polynucleotides within the elected combination, and the corresponding SEQ ID Nos for each one of the elected polynucleotides within the elected combination.

B.) ***For invention Groups drawn to "a plurality of polypeptides"*** *(including the method Groups):* Applicants are further requested to elect a single specific combination of polypeptides identified by their corresponding SEQ ID NOs. (Applicants are requested to specify the number of polypeptides within the elected combination, and the corresponding SEQ ID Nos for each one of the elected polypeptides within the elected combination.

The "Further Restrictions" are deemed proper since each one of the restrictions

would result in an amino acid sequence or a nucleic acid sequence that possesses distinct function and/or structures. The different proteins would not share the same core structure, and would also have different properties (such as 3-D folding structures and target binding properties) and therefore different functions. These different peptides or nucleic acids, or combinations thereof, do not share a common technical feature. For examples, each of the polynucleotides of SEQ ID Nos 1-3 do not share common core structure, and represent sequences for different genes. The said polynucleotides have different nucleotide sequences, and thus are structurally different from each other. Similarly, the amino acid sequences corresponding to the said polynucleotides sequences (i.e. SEQ ID Nos: 202-204) also do not share a common feature, and thus lack unity of invention. Thus, the different sets of polynucleotides or polypeptides do not share a common technical feature, and lack unity of invention.

2. The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Each group of invention has a different technical feature. For examples, the technical feature for the Group 1 invention is a set of polynucleotides; the technical feature of Group 2 is a set of polypeptides. The sets of polynucleotides are structurally different from the sets of polypeptides. Therefore, Groups 1-9 are not so linked by the same or a corresponding special technical feature as to form a single inventive concept. In addition, the special technical feature of Group 1 is known in the prior art. Ellis et al (JBC. Vol 273:1052-1057; 1998; cited in IDS) teach various polynucleotides such as the

genes for the various VEGF isoforms, Src kinase, and Yes kinase (e.g. Figure 3; p. 1052, Abstract; p. 1054, right col., "Result"), which reads on the "predictor set comprising a plurality of polynucleotides" as recited in Claim 1. Thus, the inventions lack unity.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicants are requested to further elect **a single ultimate species for <u>each</u>** of the following:

a. A single specific <u>polynucleotide</u> from the elected combination of polynucleotides identified by its specific SEQ ID No. (e.g. SEQ ID No:1). (For Groups 1, 3, 6, 8)

b. A single specific protein tyrosine kinase. (see, for example, Claim 5). (For Groups 1 and 2)

c. A single specific compound. (see, for example, Claim 6). An election of a general category such as "antisense reagents" would not satisfy this requirement. (For Groups 1-5, and 6-9)

d. A single specific polypeptide from the elected combination of polypeptides identified by its specific SEQ ID No. (e.g. SEQ ID No:202). (For Groups 2, 4, 7 and 9)

e. A single specific cell line. (see Table 1). (For Groups 5-7).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are distinct, each from the other, because their structure and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. For examples, the different polynucleotides or polypeptides are structurally and functionally different from each other. The various polynucleotides or polypeptides do not have common sequential structures, and they form different DNA or protein structures. The different kinases are structurally different proteins and thus lack unity of invention. Thus the unity of invention between each species subgroup is lacking.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. **The reply must also identify the claims readable on the elected species, including any claims subsequently added**. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Please see the above species selection for correspondence between the claims and the species selection.

The following claim(s) are generic: 1-40.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species are distinct, each from the other structurally and functionally, because their modes of action are different. Therefore, the species have different issues regarding patentability and represent patentable distinct subject matter.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be

allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
6/20/07

/Jon D. Epperson/
Primary Examiner, AU 1639